

Introduced by Senators Ortiz and Runner

March 17, 2005

Senate Constitutional Amendment No. 13—A resolution to propose to the people of the State of California an amendment to the Constitution of the State, by amending Section 6 of, and by adding Sections 8 and 9 to, Article XXXV thereof, relating to biomedical research.

LEGISLATIVE COUNSEL'S DIGEST

SCA 13, as introduced, Ortiz. Biomedical research.

The California Stem Cell Research and Cures Act, an initiative measure, establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in the cure for, or substantial mitigation of, diseases and injuries. Existing law authorizes the issuance of bonds, not to exceed \$3,000,000,000, for the purpose of funding this research.

Existing law establishes the Independent Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute. Existing law also establishes various working groups whose purposes are to make recommendations to the ICOC regarding the making of these grants and loans.

This measure would require that the chair and vice chair and any appointed member of the Independent Citizen's Oversight Committee (ICOC), the president of the institute, and any member of any working or advisory group appointed to assist the institute or its governing body be subject to conflict-of-interest requirements and reporting of financial interest requirements that are commensurate with those

required of public officials and of persons appointed to serve the National Institute of Health, and that records and meetings be subject to state open meeting and public record laws that are applicable to state agencies.

This measure would require every contract, award, grant, loan, or other arrangement entered into by the institute, the ICOC, or any other entity of state government that provides state funding or other resources for biomedical research, as defined, to ensure that these financial arrangements do not result in a gift of public funds, that loan, lease, or rental arrangement terms are consistent with market rates for rent or interest, and that any clinical treatments, products, or services resulting from the biomedical research are made available at costs affordable to low-income residents.

The measure would require these financial arrangements to provide that the state recoup the full amount of its legal and administrative costs incurred with respect to patenting and licensing activities related to biomedical research, would require that the state be provided with its share of royalties or licensing revenues, derived from the development of clinical treatments, products, or services resulting from the research, that is sufficient to repay its expenses incurred in developing these treatments, products, or services, and would also require that these royalties or licensing revenues be transmitted to the state in an amount sufficient to repay the costs of issuing bonds incurred by the state in funding the biomedical research.

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

1 *Resolved by the Senate, the Assembly concurring,* That the
2 Legislature of the State of California at its 2005-06 Regular
3 Session commencing on the sixth day of December 2004,
4 two-thirds of the membership of each house concurring, hereby
5 proposes to the people of the State of California, that the
6 Constitution of the State be amended as follows:
7 First—That Section 6 of Article XXXV thereof is amended to
8 read:
9 SEC. 6. ~~Notwithstanding~~ *Except as otherwise provided in this*
10 *article, notwithstanding* any other provision of this Constitution
11 or any law, the institute, which is established in state
12 government, may utilize state issued tax-exempt and taxable
13 bonds to fund its operations, medical and scientific research,

1 including therapy development through clinical trials, and
2 facilities.

3 Second—That Section 8 is added to Article XXXV thereof, to
4 read:

5 SEC. 8. (a) The chair and vice chair and any appointed
6 member of the Independent Citizen's Oversight Committee
7 (ICOC), the president of the institute, and any member of any
8 working or advisory group appointed to assist the institute or its
9 governing body, is subject to conflict-of-interest requirements
10 and reporting of financial interest requirements that are
11 commensurate with those required of public officials and of
12 persons appointed to serve the National Institute of Health.

13 (b) Meetings and records of the institute, the ICOC, or any
14 body established to govern the institute, and any working or
15 advisory group, are subject to California open meeting and public
16 record laws that are applicable to state agencies.

17 Third—That Section 9 is added to Article XXXV thereof, to
18 read:

19 SEC. 9. (a) Every contract, award, grant, loan, or other
20 arrangement entered into by the institute, the Independent
21 Citizen's Oversight Committee, or any other entity of state
22 government that provides state funding or other resources for
23 biomedical research, shall ensure all of the following:

24 (1) Notwithstanding Section 6, the contract, award, grant,
25 loan, or other arrangement does not result in a gift of public
26 funds within the meaning of Section 6 of Article XVI.

27 (2) All clinical treatments, products, or services resulting from
28 the biomedical research are made available at costs affordable to
29 low-income residents, including health care and preventive
30 health programs, funded in whole or in part by the State and
31 counties, that serve low-income residents.

32 (3) The terms of any loan, lease, or rental arrangement are
33 consistent with market rates for rent or interest.

34 (4) The State recoups the full amount of its legal and
35 administrative costs incurred with respect to patenting and
36 licensing activities related to the biomedical research.

37 (5) The State is provided a share of the royalties or revenues,
38 derived from the development of clinical treatments, products, or
39 services resulting from the research, that is sufficient to repay its

1 expenses incurred in developing the clinical treatments, products,
2 or services.

3 (6) In addition to royalties or licensing revenues described in
4 paragraph (5), royalties or licensing revenues are transmitted to
5 the State in an amount sufficient to repay any costs of issuing
6 bonds incurred by the State in funding the biomedical research.

7 (b) Nothing in this section shall be construed to preclude the
8 State from receiving any other benefits to which it would
9 otherwise be entitled under Chapter 3 (commencing with Section
10 125290.10) of Part 5 of Division 106 of the Health and Safety
11 Code, or its successor.

12 (c) For purposes of this section, “biomedical research” means
13 research that has as its purpose increasing the understanding of
14 human diseases and conditions and improving treatments for
15 these diseases and conditions.